

## **REMARKS**

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In the accompanying amendment, claims 1, 4-5, 8. and 9-11 are cancelled. New claim 14 is added. The amendments to the claims are supported by the original filed specification, claims, and drawings. Thus, it is respectfully submitted that the amendments to the claims do not add new matter.

### **Claim Objections**

Given that claim 1 has been cancelled, the Examiner is respectfully requested to withdraw the objection to claim 1.

### **Claim Rejections under 35 USC §103**

Claims 1, 5, 8, and 11 stand rejected under 35 USC 103(a) as being unpatentable over Ebert et al. (WO 95/24172) (pub. Sept. 14 1995) in view of Visser et al. (WO 98/56325) (pub. Dec. 17, 1998).

Applicant traverses.

Claim 15 recites the following limitations:

A patch device, comprising:

a composite distal layer comprising a first distal layer and a second distal layer adhesively secured together; wherein the second distal layer is impervious to dimethylformamide (DMF) and a transverse passage is formed to extend transversely through the first and second distal layers ;

a proximal layer adhesively secured to the composite proximal layer to form a cavity together with the proximal layer; said cavity holding a substance to be administered to a patient; a composition and thickness of the proximal layer being selected so that its permeability to an irritating component of said substance is less than the permeability of human or animal skin to such irritating component, thereby to reduce irritation of the human or animal skin; and

a backing sheet on which the composite distal layer is mounted via the first distal layer, the backing sheet comprising a peripheral area around the composited distal layer, said backing layer comprising an access port to provide access the transverse passage of the composite distal layer for introduction of a substance into the cavity via a syringe; and an adhesive coating protected with a cover which is removable to allow the patch device to be secured to the skin of the human or animal patient.

(Claim 15, underlining for emphasis)

The transdermal patch of Ebert does not disclose the limitation of a backing sheet having a peripheral area by which the patch may be adhered to a patient and an access port via which a syringe may be used to inject a substance into the cavity formed in the patch.

Visser and Landauer also fail to disclose the limitation of a backing sheet,

Regarding the limitation of the access port and the transverse passage. Landauer merely describes that indirect administration of DMF may be done by introducing a known amount of DMF with a syringe into the silicon dioxide adsorbent after the patch has been applied to the skin (p. 17). However, Landauer does not describe the structures of an access port or a passage. It is possible to perform the indirect administration of DMF as described by Landauer in a patch with no access port or transverse passage, but it may be difficult and may require more force.

Based on the foregoing, it is respectfully submitted that claim 14 is not obvious in view of Ebert and Visser or Ebert, Visser, and Landauer because these combinations of references do not teach or suggest all limitations of claim 14.

Given that claims 1, 4, 6-8, depend on claim 14, it is respectfully submitted that these claims are also not obvious in view of the art of record.

Claims 10 stands rejected under 35 USC 103(a) as being unpatentable in view of Ebert, Visser, Landauer, and Reed (US 5,827,530). Applicant traverses this rejection on the basis of the above arguments.

#### Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (650) 7965417 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 503437.

Respectfully submitted,

Quinton Van Rooyen et al.

By their Representatives,  
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